

K003501 N PROTEIN STANDARD UY CALIBRATORMar 15, 2001
122 days to decisionK003501 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k003501/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator, Secondary (JIT) |
| Date received | Nov 13, 2000 |
| Decision date | Mar 15, 2001 |
| Days to decision | 122 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dade Behring, Inc. |
| Location | Newark,, DE, US |
| Contact | REBECCA S AYASH |
| 510(k) history | 343 submissions · 343 cleared · 1978-2010 |

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